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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,647	YONEDA ET AL.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed June 29, 2006 presents an election of Group II claims 14-21 with traverse is herein acknowledged.

The traversal is on the grounds that Groups I and II, are not directed to different invention because the Office has not provided reasons and/or examples to support that the process "of treating or preventing an inflammatory disease can be practiced with a corticosteroid" and further, that the Office has failed to show that the proposed use of the claimed product is materially different from the claimed use.

In response, Examiner respectfully reiterates the restriction is proper when the claimed method can be used by a materially different product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating or preventing an inflammatory disease can be practiced with a corticosteroid. A corticosteroid is not an ornithine and is well known in the art as an anti-inflammatory agent. Therefore, Applicant's argument is not found persuasive.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 29, 2006. This application contains claim 1-13 drawn to an invention

nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP 821.01.

Claims 14-21 are under consideration.

Claim Rejections - 35 USC § 11 2

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any : person skilled in the ad to which it pertains, or with which It is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing inflammatory diseases. The claim contains subject matter was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the specification is enabled for the treatment of some inflammatory diseases, it does not provide sufficient information that inflammatory diseases are preventable using the method of administering an effective amount of ornithine and/or one or more branched amino acids to a subject in need thereof.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set

forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention, (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims', (6) the amount of direction or guidance presented', (7) the presence or absence of working examples', and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1). The Nature of the Invention: the rejected claims 14-21 are drawn to, "a method for treating or preventing an inflammatory disease which comprises administering an effective amount of ornithine and/or one or more branched amino acids to a subject in need thereof. "

(2). The state of the prior art: In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of **preventing** an inflammatory disease. The state of the art for the treatment of inflammatory diseases is relatively high.

(3). The predictability or unpredictability of the art: the art does not enable a person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation.

The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing an inflammatory disease. The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not as of yet reasonably possible with most diseases/disorders, the specification is viewed as lacking an adequate enablement of where inflammatory diseases may be actually prevented.

(4). The breadth of the claims: the claims encompass a method for treating or preventing an inflammatory disease which comprises administering an effective amount of ornithine and/or one or more branched amino acids to a subject in need thereof. Applicant fails to set forth the criteria that define prevention of the disease. Thus, the breadth of the claim is over broad.

(5). The amount of direction or guidance presented: does not provide any guidance in terms of preventing an inflammatory disease.

(6). The presence or absence of working examples: while applicant is enabled for the treatment of some inflammatory diseases, applicant does not provide any working examples for the prevention of an inflammatory disease. The applicant has not provided

any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition.

(7). The quantity of experimentation necessary: the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples, "the level of skill in the art' and "predictability" etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

In view of the breadth of the claims, unpredictability of preventing an inflammatory disease, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

The burden of enabling one skilled in the art to prevent an inflammatory disease would be much greater than that enabling the treatment. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing an inflammatory disease. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed compound ornithine and/or one or more branched amino acids for preventing an inflammatory disease.

Claims 14-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treatment of all inflammatory diseases. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the specification is enabled for the treatment of some inflammatory diseases, it does not provide sufficient information that all inflammatory diseases, are treatable using the method of administering an effective amount of ornithine and/or one or more branched amino acids to a subject in need thereof. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

Analysis of In re Wands are listed below:

(1). The Nature of the Invention: Claims 14-20 are drawn to an invention which pertains to "a method for treating or preventing an inflammatory disease which comprises administering an effective amount of ornithine and/or one or more branched amino acids to a subject in need thereof."

(2). The state of the prior art: The state of the art regarding treating inflammatory diseases is relatively high.

(3). The predictability or unpredictability of the art: The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for treatment of all inflammatory diseases. Various inflammatory diseases require different therapies, and take into consideration various factors. Thus, the state of the art is unpredictable. Further, the specification is viewed as lacking an adequate enablement of where all inflammatory diseases may be actually treated.

(4). The breadth of the claims: the claims encompass a method for treating or preventing an inflammatory disease which comprises administering an effective amount of ornithine and/or one or more branched amino acids to a subject in need thereof. Applicant fails to set forth the criteria that define the treatment of all the diseases.

(5). The amount of direction or guidance presented: While the specification is enabled for the treatment of some inflammatory diseases such as chronic rheumatism, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of treating inflammatory diseases such cancer, AIDs, Crohn's disease, etc. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed compound ornithine and/or one or more branched amino acids for treatment of all inflammatory diseases.

(6). The presence or absence of working examples: Applicant does not provide any working examples for the treatment of all inflammatory diseases. The applicant has not

provided any competent evidence or disclosed any tests that are highly predictive for the treatment effects of the instant composition.

(7). The quantity of experimentation necessary: The quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples," "the level of skill in the art" and "predictability" etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

In view of the breadth of the claims, unpredictability of treatment all inflammatory diseases, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention of claims 14-21.

The claims are treated on their merits pertaining to the treatment of inflammatory diseases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The instant claims are directed to a method for treating and preventing an inflammatory disease, which comprises administering an effective amount of ornithine and/or one or more branched amino acid to a subject.

Claim 14-16, 20, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Moretti (WO 97/05862).

Moretti discloses the oral or parenteral administration of the amino acid ornithine in the treatment of inflammatory bowel disease, hepato-splenomegaly associated with inflammatory disease, rheumatoid arthritis, and connective tissue disease (inflammatory diseases) (see claims 1,2,4,12-14, and 15; p. 9-11).

Claim 14-17, and 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Meisner (US Pat No. 4,772,591).

Meisner discloses an amino acid used in a composition to treat tissue degenerative inflammations and inflammatory diseases is valine (branched amino acid) (column 4, lines 42-60). The composition is administered topically and orally (column 6, lines 15 and 40). In the oral form, the substance mixture is formulated into pharmaceutically acceptable dosage forms such as powders, tablets, or capsules (see column 6, lines 45-49).

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Akimoto et al. (Pat No. 5,834,512).

In the Background of the Invention, Akimoto et al. discloses through incorporation of a reference that a leucine (branched amino acid) derivative is used for the treatment of "allergic diseases such as bronchial asthma, various inflammatory diseases, ischemia-reperfusion disorders (column 2, lines 54-60)."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moretti (WO 97/05862) as applied to claims 14-16, 20, 21 above, and further in view of Fischer et al. (US Pat. No. 3,950,529) and Ansel et al.

Moretti et al. is as discussed above.

Moretti et al. does not teach ornithine and/or branched amino acids are in a food or a drink.

Fischer teaches an amino acid formulation comprised of isoluecine, leucine, and valine formulated for intravenous or oral administration (see abstract). For oral consumption, the amino acid mixture, are made into edible food preparations in the form of palatable liquid drinks or semisolid foods.

Additionally, Ansel et al. teaches, "solid dosage forms are best taken with a glassful of water or a beverage. Further, the reference teaches an ordinary tablet

crushed or a capsule opened helps "facilitate ease of administration, any unpleasant drug taste may be masked by mixing with custards, yogurt, rice pudding, other soft food, or fruit juice (p. 227, column 2, paragraph 5)."

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer ornithine and/or branched amino acids with a food or drink because Morreti et al. teaches amino acid compositions comprising leucine, isoleucine, and valine incorporated with food preparations. The motivation to administer ornithine and/or branched amino acids with a food or drink is because Ansel et al. teaches that for ease of administration and avoidance of unpleasant tastes drugs may be administered with various foods and drinks. Therefore, a skilled artisan would have reasonable expectation of success in incorporating ornithine and/or branched amino acids with a food or drink.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER